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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/752,411 | 01/07/2004 | Karen Jackson | 330499.00025 | 4891 |

27160 7590 01/28/2008

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| EXAMINER | |
|---|---|
| KUDLA, JOSEPH S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1611 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 01/28/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/752,411 | JACKSON, KAREN | |
| | Examiner | Art Unit | |
| | Joseph S. Kudla | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *64 and 129-152* is/are pending in the application.

4a) Of the above claim(s) *135-138,141-142 and 144-147* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64,129-134,139,140,143 and 148-152* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's September 19, 2007 correspondence elects Group IV, without traverse, which encompasses claims 64-65. Claims 1-63 and 65-128 have been cancelled which represented inventions I-III, V and part of IV. Claim 64 has been amended and new claims 129-152 have been added [Note: Applicant's September 19, 2007 correspondence incorrectly discloses new claims 129-189 have been added.]. Applicant failed to address the election of species requirement from the Restriction/Election correspondence dated August 22, 2007. Applicant's October 29, 2007 correspondence elected morphine as the opioid species, corn starch as the filler species and docusate sodium as the surfactant. Within the instant claim set for the elected invention, claims 135-138 are directed towards opioid species in claim 64; however, claim 64 does not contain an opioid reference. Therefore, claims 135-138 are withdrawn from consideration as being drawn to non-elected subject matter see 37 CFR 1.142(b). Claims 141-142 and 144-147 are withdrawn from consideration as being drawn to non-elected subject matter (docusate sodium is an hydrophilic anionic surfactant) see 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 64, 129-134 and 148-152.

### *Priority*

2. This application is continuation of 10/349,431, filed January 22, 2003, a continuation-in-part of 10/108,659, filed March 27, 2002, a continuation-in-part of

10/035,962, filed January 22, 2002 and claims foreign priority from application EP 0201367.0, filed January 22, 2002.

3. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 10/349,431, 10/108,659, 10/035,962, filed January 22, 2002 and foreign application EP 0201367.0, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. All claims are not adequately supported or enabled by the prior-filed applications for a process of manufacturing.

It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the previous referred filings does not support the granting of an earlier filing date. Specifically, the prior filings do not support a process of manufacture. All claims are given a priority date of January 7, 2004.

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Union on January 22, 2002. It is noted, however, that applicant has not filed a certified copy of the EP 0201367.0 application as required by 35 U.S.C. 119(b).

5. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in European Union on January 22, 2002. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

***Information Disclosure Statement***

6. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on February 10, 2005 is acknowledged.

7. The information disclosure statement filed on May 20, 2005 does not fully comply with the requirements of 37 CFR 1.98(b) because: The reference pertaining to Beglinger fails to include a publication date. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b). Failure to timely comply with this notice will result in the above

mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

***Application Disclosure Sheet***

8. The year for the foreign priority application is incorrect. Specifically, the date is disclosed as January 22, 202. It is believed that Applicant intended the year to be 2002.

Appropriate action is required.

***Specification Objections***

***Abstract***

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

(1) if a machine or apparatus, its organization and operation;

(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;

(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

9. The abstract discloses a method of treatment and a pharmaceutical composition; however, there is no mention of a process of manufacture for devazepide and a surfactant.

Appropriate action is required.

## *Specification*

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

10. The specification of a utility application should include the above sections in order. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading. Specifically, none of the section headings, nor disclosure of a cross-reference to priority or nor a disclosure of joint research agreements are present.

Appropriate action is required.

***Title***

11. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: PROCESS OF MANUFACTURE OF DEVAZEPIDE COMPOSITIONS.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 64, 129-134 and 148-152 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide adequate written description for the process of manufacture of devazepide with any surfactant, specifically docusate sodium. To claim the process of manufacture of devazepide with a surfactant, Applicants' specification is required to demonstrate the process of manufacture by enumerating the steps involved in manufacturing the pharmaceutical composition. The parameters such as processing steps (milling, granulation, sieving, blending, etc.) as well as testing indications (demonstrating flow characteristics, particle size data, content uniformity, etc.) should be disclosed to demonstrate a full written description that Applicant is claiming as her own. Without this disclosure, Applicant lacks adequate written description.

13. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language "up to 0.7 mg/kg/day" in line 5 of claim 64 is indefinite. The assumption is that "up to" represents a range. Conceivably, the range extends to 0.0 mg/kg/day of devazepide, which negates the devazepide in the claim and leaves the Examiner to question the meaning of the invention Applicant claims, thereby rendering the subject matter of the instant claim unclear.

The language "providing a suitable amount" in line 6 of claim 64 is indefinite. The Examiner is unable to ascertain from the instant specification what a suitable amount is. Without further disclosure from Applicant, the phrase is unclear and confusing.

14. Claim 64 recites the limitation "the surfactant" in line 7. There is insufficient antecedent basis for this limitation in the claim.

15. Claims 64, 129-134 and 148-152 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a process of manufacture of devazepide and a surfactant.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation to manufacture a pharmaceutical composition of devazepide and a surfactant.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)*. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

The breadth of the instant claims is extremely broad in scope for the types of processing steps that could be performed in the manufacture of a pharmaceutical composition of devazepide and a surfactant. Applicant has not provided sufficient evidence to support a claim set drawn to a process of manufacturing outlined in the instant claim set. The breadth of the claims exacerbates the complex nature of the subject matter to which the present claims are directed.

**The nature of the invention**

The instant claim set outlines a process of manufacture of devazepide and

a surfactant. Daily dosages and physical forms of the devazepide are disclosed. Docusate sodium and starch are identified as the surfactant and filler in the pharmaceutical composition, respectively. Additionally, two compositions and the weights of the devazepide, surfactant and filler are disclosed.

**The state of the prior art**

Prior art in the field shows it is known that CCK antagonists, such as devazepide, are relatively water-insoluble compounds and that for the CCK antagonist to be administered it would need to be formulated with a satisfactory carrier (Iversen, WIPO Application number WO 99/18967 and cited by applicant, page 2, lines 9-20). The prior art is silent on the ability of docusate sodium, acting as a surfactant, to impart special physical properties when used to form a pharmaceutical composition with devazepide.

**The amount of direction provided by the inventor and the existence of working examples**

The instant specification does not provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to practice the claimed methods commensurate in the scope with the instant claims. Applicant provides *no* guidance or examples on the process of manufacture of the pharmaceutical composition. Adequate enablement requires more than a mere statement of a process for the manufacture of a pharmaceutical composition. Adequate guidance that would

serve to enable the invention would be disclosure of specific processing steps (e.g., granulation, sieving, blending) with defined amounts of material and then demonstration that the process controls were adequate and reflected a manufacturing process that was repeatable (e.g., content uniformity, particle size, composite assay, etc.). Applicant has no disclosure of these parameters.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation (*In re Wright, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993)*). The specification lacks sufficient disclosure to support applicant's claims of a process of manufacture for a pharmaceutical composition of devazepide and a surfactant. There is not seen sufficient working examples or data from references in the prior art providing a nexus between that which applicant asserts to support a process of manufacture and the amount of disclosure Applicant has actually provided.

**The quantity of experimentation needed to make and use the invention based on the content of the disclosure**

Based on the unpredictable nature of the invention, the state of the prior art and the breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation. The essential elements towards the validation of a manufacturing process require close attention to process controls and analytical testing

to confirm results. Pharmaceutical formulation has always been more of an art than a science. The physical properties that are theoretically expected when combining excipients and active substances are not the "real world" results one usually obtains. Obtaining the best formulation is often done through a series of adjustments to arrive at a final formulation.

Based on the unpredictable nature of the invention, the state of the prior art and the extreme breadth of the claims, one skilled in the art could not practice the claimed invention without undue experimentation.

***New Matter***

16. The amendment filed September 19, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original specification does not support a process of the manufacture of a pharmaceutical composition. The instant disclosure makes *no* mention of a "process" in conjunction with the word manufacture in the instant specification. In no instance in the instant disclosure has a process for the manufacture of a composition been indicated.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 64, 129-130, 139-140, 143 and 148-152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iversen (WIPO Application number WO 99/18967 and cited by applicant), in view of Remington's Pharmaceutical Sciences (Mack Publishing Co., 1975, 15th edition, pages 295-296 and 1266).

Iversen teaches that CCK antagonists are relatively water-insoluble compounds and that for the CCK antagonist to be administered, the CCK antagonist would need to be formulated with a satisfactory carrier (page 2, lines 9-20 of the reference). Iversen also teaches a preferred CCK antagonist is devazepide (page 6, line 5).

Iversen does not teach the use of docusate sodium as a surfactant or corn starch as a filler to form a pharmaceutical composition.

Remington's Pharmaceutical Sciences compendium teaches common useful pharmaceutical excipients (e.g., docusate sodium and corn starch) for use in formulation pharmaceutical compositions. Docusate sodium is useful as a surfactant (pages 295 and 296 under Anionic Agents). Docusate sodium is included within the group dialkyl sodium sulfosuccinates (page 296, column 1, paragraph 3, lines 7-8). Corn

starch, which is included within the genus of starch, is useful as a filler (page 1266, column 2, under Starch, under Uses, line 3).

It would have been obvious to one of ordinary skill in the art that if one sought a method of manufacturing a pharmaceutical composition that included a relatively insoluble compound, a surfactant such as docusate sodium would have been an obvious choice useful in increasing the solubility. In addition, it would also have been obvious to one of ordinary skill in the art that if one sought a method of manufacturing a pharmaceutical composition and was in need of a fill excipient to disperse the active substance, an insipid filler such as corn starch would have been an obvious choice in decreasing powder load.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.). Therefore, no more than routine experimentation would have been necessary to one of ordinary skill in the art to arrive at both the administration

dosages recited in instant claims 129 and 130 and an optimal formulation for producing a liquid or solid, as in instant claims 131-134 and claims 151 and 152.

Therefore, the teachings of Iversen, in view of Remington's Pharmaceutical Sciences, render the claimed invention obvious.

No claims allowed.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

1/21/08